emdeon™

65 East State Street
Suite 1800
Columbus, OH 43215
614.462.5435
614.462.5470 fax

February 28, 2006

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments of Emdeon Corporation --- Consumer-Directed Promotion of Regulated Medical Products; Public Hearing, Docket No. 2005N–0354

To Whom it May Concern:

Emdeon Corporation ("*Emdeon*") commends the Food and Drug Administration ("FDA") of the Department of Health and Human Services ("*HHS*") for seeking public input on direct-to-consumer (DTC) promotion of regulated medical products, including prescription drugs for humans and animals, vaccines, blood products, and medical devices. In that regard, we understand that the "FDA is particularly interested in hearing the views of individuals and groups most affected by DTC promotion, including consumers, patients, caregivers, health professionals (physicians, physicians' assistants, dentists, nurses, pharmacists, veterinarians, and veterinarian technicians) managed care organizations, and insurers, as well as the regulated industry."[1]

I. Introduction

Emdeon is comprised of three business units, each of which is a national leader in providing health care information services and technology solutions for participants across the health care continuum:

- Emdeon Business Services is the health care industry's leading clearinghouse for electronic health care transactions, processing over 2 billion transactions per year. More than 300,000 medical and dental providers, 5,000 hospitals, 36,000 pharmacies and laboratories, and 600 information system software vendors rely on Emdeon Business Services to connect to nearly 1,200 commercial and governmental health care plans. Emdeon Business Services provides software services to several federal agencies, including CMS.

2005 N-0354 C 15

[1] 70 Fed. Reg. 54054 (September 13, 2005)

- Emdeon Practice Services is the leading national provider of integrated physician practice and clinical management systems, supporting thousands of practices sites nationally.

- WebMD Health Corp., a public subsidiary of Emdeon, is a leading provider of health information services to consumers, physicians, healthcare professionals, employers and health plans through our public and private online health portals. The online healthcare information, decision-support applications and communications services that we provide are designed to help consumers and healthcare professionals make more informed healthcare decisions, by: enabling consumers to obtain detailed information on a particular disease or condition, analyze symptoms, locate physicians, store individual healthcare information, receive periodic e-newsletters on topics of individual interest, enroll in interactive courses and participate in online communities with peers and experts; make it easier for physicians and healthcare professionals to access clinical reference sources, stay abreast of the latest clinical information, learn about new treatment options, earn continuing medical education credits and communicate with peers; and, enable employers and health plans to provide their employees and plan members with access to personalized health and benefit information and decision-support technology that helps them make more informed benefit, provider and treatment choices.

Given its connectivity infrastructure and the extent of its broad spectrum of consumer-centric technologies, Emdeon is committed to working with the FDA in this important area.

II. Comments

- We believe that DTC advertising about prescription drugs can: (1) inform consumers about health conditions and available treatment options (2) enable consumers to take an active role in managing their health and (3) enhance the physician-patient relationship.

- A growing body of research and expert opinion in both the public and private sectors supports the view that the majority of the information disseminated by DTC advertising is done so in an accurate, non-misleading, balanced and understandable manner.

- Public debate should focus on ensuring that the information disseminated by DTC advertising is balanced and presented in a comprehensive manner so that consumers receive a complete understanding of the desired benefits and potential risks of the particular treatment option.

- The use of the Internet for DTC advertising fully supports the need for complete and balanced information in a manner that is consistent with President George W. Bush's vision for the future of health care. In fact, it is this type of communication—one that improves "the quality and efficiency of health care and the ability of consumers to manage their care and safety"—that is envisioned by the United States Department of Health and Human Services and the Office of the National Coordinator for Health

Information Technology ("ONCHIT") in its Mission Statement for health information technology.

- FDA has a number of formal and informal enforcement tools available – from issuing informal regulatory and "warning" letters to formal seizure, injunction, and criminal actions against the misbranding of drug and biologic products. When a DTC advertisement or material violates FDA's extensive legal and regulatory scheme governing promotional labeling and advertisements, the agency should determine which enforcement mechanism is most appropriate and promptly take action.

- Informal actions such as regulatory and warning letters are effective in bringing about the withdrawal of violative promotional labeling or advertising and, in certain circumstances, in the publication of corrective advertising by the manufacturer. *See* General Accounting Office Report, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations" (Oct. 2002) at 24 (reporting that pharmaceutical companies comply with agency requests to cease dissemination of misleading advertisements).

- We believe that FDA can and should continue to work with the pharmaceutical industry as well as advertisers to identify advertising issues that affect the public health and address those issues cooperatively in the first instance. Rather than considering new or different enforcement remedies,[2] FDA should dedicate adequate resources to carry out its existing responsibilities and continue to pursue remedial actions when warranted.

If you have any further questions or desire further information, please do not hesitate to contact me at 614-462-5435 or bmarotta@emdeon.com.

Respectfully submitted,

Robert D. Marotta
Senior Vice President & Regulatory Counsel

[2] It is well-settled that commercial speech, such as DTC advertising, receives First Amendment protection, see Thompson v. Western States Med. Ctr., 535 U.S. 357, 366 (2002) (citing Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 765 (1976)); see also Bigelow v. Virginia, 421 U.S. 809, 818 (1975) (stating that "speech is not stripped of First Amendment protection merely because it appears" as a paid commercial advertisement), and that publishers have a First Amendment right to accept or reject advertisements as they see fit, see Miami Herald Pub. Co. v. Tornillo, 418 U.S. 241, 257 (1974) (finding unconstitutional law compelling newspaper to publish reply from attacked candidate); Associates & Aldrich Co. v. Times Mirror Co., 440 F.2d 133, 135 (9th Cir. 1971) (finding that newspaper could not be compelled to publish advertisement). In light of these precedents, new or different enforcement approaches for DTC advertisements should be carefully assessed in light of First Amendment protections afforded to both advertisers and publishers.